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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,431	09/17/2007	James Birchall	85189-13400	1867

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WINSTON & STRAWN LLP
PATENT DEPARTMENT
1700 K STREET, N.W.
WASHINGTON, DC 20006

EXAMINER

OSINSKI, BRADLEY JAMES

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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03/02/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@winston.com
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Office Action Summary

Application No.

10/597,431

Applicant(s)

BIRCHALL ET AL.

Examiner

BRADLEY J. OSINSKI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/30/2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1, 3-7, 9-21 and 23-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avrahami et al (2003/0208152) in view of Eggers et al (7,505,812).

a. Regarding claims 1 and 16, Avrahami discloses a method of delivering an oligonucleotide or polynucleotide via the following: generating at least one micro-channel in the skin of a subject (Paragraph 17) and applying to the skin a pharmaceutical composition of an acceptable carrier (conductive substance - Paragraph 32) with an active ingredient (Paragraph 33) of an oligonucleotide or

polynucleotide (Paragraph 255). Avrahami also discloses two different subsets for generating the micro-channels (Paragraph 55-58).

While Avrahami substantially discloses the method as claimed, it does not specifically disclose generating a second plurality of micro-channels in the same area of skin to facilitate transdermal delivery of the carrier. However, Avrahami does disclose further transport facilitation via iontophoresis or electroporation (Paragraph 217). Whether or not iontophoresis or electroporation generate more micro-channels is debatable. However, Eggers discloses an electrosurgical system to open or maintain patency of openings (Col.2 lines 66 and 67) that is also used for ablating the corneum stratum (starting on Col.7 line 51). One of ordinary skill in the art is aware that restenosis is the narrowing of passages after treatment. Eggers also uses radio frequencies preferably between 50 kHz and 1Mhz (Col.8 line 47), compared to the 1 kHz-300 kHz disclosed by Avrahami (Paragraph 136). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the usage of the device of Avrahami to also apply its electrical field after initially ablating tissue as suggested by Eggers in order to maintain the patency of the newly created channels.

b. Regarding claims 3 and 17, Avrahami specifically discloses agents based on DNA and RNA (Paragraph 257).

c. Regarding claims 4, 6, 18 and 20, insulin is specifically disclosed in paragraph 253.

- d. Regarding claims 5 and 19, many different drugs are disclosed in paragraphs 234-257, including many regulatory drugs. Paragraph 253 is of particular interest.
- e. Regarding claims 7 and 21, Avrahami discloses antisense RNA (Paragraph 257).
- f. Regarding claims 9 and 23, the apparatus is disclosed and has an electrode cartridge/skin patch and a main/control unit coupled to the patch that supplies electrical energy to the electrodes (Paragraph 17). This causes ablation of the stratum corneum which results in micro-channels (Paragraph 18).
- g. Regarding claims 10 and 24, Avrahami does not specifically state that the micro-channels are of uniform shape and dimensions. However, the Examiner takes the position that this is implicit in the disclosure of Avrahami. Since the electrodes are not disclosed as being of differing sizes and shapes, one of ordinary skill in the art would assume they are uniform. The micro-channels are formed by the electrodes and electricity and thus since the electrodes and electricity are uniform across the device, the micro-channels will be of uniform shape and dimension. While the Examiner believes the micro-channels are generated with a uniform shape and dimension (as stated and explained above) a backup rejection is made here. It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate micro-channels of uniform shape and dimension so as to homogenously deliver the active agent

which is notoriously well known within the art as being more desirable than uneven delivery absent any other considerations.

h. Regarding claims 11-14 and 25-28, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to determine and assign diameters and lengths to the electrodes because Applicant has not disclosed that such a limitation provides an unexpected advantage, is used for a particular purpose or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Avrahami because both Avrahami and Applicant's invention are used for the same purpose and in the same manner and also since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (CCPA 1955). Therefore, it would have been an obvious matter of design choice to modify Avrahami to obtain the invention as specified in claims 11-14, 25-28 and 32-35.

i. Regarding claim 15 and 29, Avrahami discloses the current as having a frequency of 1 kHz to 300 kHz which overlaps with the radio frequency which is 3 kHz to 300 GHz.

2. Claims 8 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avrahami et al (2003/0208152) and Eggers et al (7,505,812) as applied to claim 1 above, and further in view of Monahan et al (6,429,200).

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j. Regarding claims 8 and 22, while Avrahami substantially discloses the apparatus as claimed, it does not disclose additives to the active agent such as lipids, polycations or nuclease inhibitors. However, Monahan discloses adding polycations to polynucleotides and reverse micelles in order to compact the polynucleotide which is advantageous for gene therapy (Col. 5 lines 31-54). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the delivery device/method of Avrahami to utilize polycations and reverse micelles as taught by Monahan to compact the polynucleotides for gene delivery purposes.

Response to Arguments

3. Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767
/KEVIN C. SIRMONS/

Supervisory Patent Examiner, Art Unit 3767